**Retrospective Evaluation** 

# Comparison between Balloon Kyphoplasty and Short Segmental Fixation Combined with Vertebroplasty in the Treatment of Kümmell's Disease

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Free full manuscript: www.painphysicianjournal. com **Background:** Kümmell's disease is a clinical syndrome characterized by a minor spinal trauma with a symptom-free period from months to years, followed by progressive painful kyphosis. Kyphoplasty and vertebroplasty have been introduced to treat Kümmell's disease, and obtained good clinical results. Recently, delayed cement displacement was reported for Kümmell's disease treated by cement augmentation alone. Some authors recommended internal fixation combined with cement injection for this particular condition.

**Objective:** To evaluate and compare the clinical efficacy, especially the pain reduction, of 2 procedures (kyphoplasty alone versus short segmental fixation combined with vertebroplasty) in the treatment of Kümmell's disease.

**Study Design:** Retrospective evaluation and comparison of postoperative VAS scores and radiographic outcomes.

**Setting:** Single center inpatient population.

**Methods:** Two procedures, including conventional balloon kyphoplasty and short segmental fixation combined with vertebroplasty, were utilized for 54 patients with Kümmell's disease. All patients were followed-up for 8 – 42 months. Visual analog scale (VAS), vertebral height, and local kyphotic angle were evaluated and compared for 2 groups before surgery, after surgery, and at final follow-up. Pearson correlation coefficients were calculated to assess the relationship between the decreased values of pain scores (VAS) and improvement of anterior vertebral height and local kyphotic angle.

**Results:** For the KP group, the VAS pain score decreased significantly from 7.8  $\pm$  0.9 before surgery to 3.3  $\pm$  1.0 after surgery (P < 0.01), and 2.9  $\pm$  0.9 at final follow-up (P < 0.01). The mean height of the anterior vertebral body increased from 14.8  $\pm$  2.4 mm before surgery to 19.3  $\pm$  2.1 mm after surgery (P < 0.01). The mean local kyphotic angle decreased from 22.7  $\pm$  6.9° before surgery to 14.5  $\pm$  5.3° after surgery (P < 0.01). For SSF + VP group, the VAS pain score decreased significantly from 7.2  $\pm$  1.6 before surgery to 4.7  $\pm$  1.3 after surgery (P < 0.01), and 3.5  $\pm$  1.2 at final follow-up (P < 0.01). The mean height of the anterior vertebral body increased from 13.6  $\pm$  2.5mm before surgery to 17.3  $\pm$  2.7 mm after surgery (P < 0.01). The mean local kyphotic angle decreased from 24.7  $\pm$  9.2° before surgery to 15.5  $\pm$  6.2° after surgery (P < 0.01). No significant loss of correction of vertebral height and kyphosis was observed at follow-up. Improvement of VAS score had no correlation with improvement of vertebral height or local kyphotic angle. Asymptomatic cement leakage occurred in both groups.

Limitations: Retrospective study with a relatively small sample size.

**Conclusions:** This study showed that both balloon kyphoplasty alone and short segmental fixation combined with vertebroplasty for Kümmell's disease were safe and effective. Improvement of VAS score had no correlation with improvement of vertebral height or local kyphotic angle. Comparatively, balloon kyphoplasty resulted in same the clinical outcomes with less complications.

Key words: Kümmell's disease, kyphoplasty, vertebroplasty, short segmental fixation, pain

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n 1895, German surgeon Herman Kümmell named a rare type of osteoporotic vertebral fracture in which patients suffered a minor spinal trauma but resulted in a symptomatic, progressive, angular kyphosis after a symptom-free period of time ranging from months to years. With the development of radiographic and medical technology, reported cases of Kümmell's disease have been gradually increasing in the last 20 years. The commonly accepted definition of Kümmell's disease is a microtrauma which leads to osteonecrosis and delayed vertebral collapse, mostly occurring in the thoracolumbar spine (1,2). There are 5 stages of Kümmell's disease according to the Steel classification, and 3 stages according to the Li classification (3). Controversy still remains regarding etiological factors, diagnostic criteria, clinical stages, and treatment strategy (4,5). The percutaneous minimally invasive techniques of vertebroplasty and balloon kyphoplasty have been introduced into clinical practice to treat this disease during the past several years (6,7). Some studies have recommended cement augmentation combined with short segmental fixation for Kümmell's disease because of the lack of cement diffusion in this special condition (8,9). Up to now, articles have been limited to case reports and small series of patients. We evaluated one group (KP group) of 31 patients with Kümmell's disease treated by kyphoplasty alone and another group (SSF + VP group) of 23 patients treated by open short segmental fixation combined with vertebroplasty. The aim of this study was to evaluate and compare the clinical efficacy, especially the pain reduction, of these 2 procedures in the treatment of Kümmell's disease.

#### METHODS

#### **Case Information**

This study included 2 groups of patients with Kümmell's disease, the KP group and SSF + VP group. The KP group consisted of 31 patients, 6 men and 25 women, aged 61 – 83 years (average, 72.6 years). The mean bone mineral density of the lumbar spine was -3.45 standard deviation (SD). Fourteen patients had hypertension and 6 had diabetes mellitus. The treated levels included T11 (n = 6), T12 (n = 15), L1 (n = 8), and L2 (n = 2). The SSF + VP group included 23 patients, 3 men and 20 women, age 64 – 76 years (average, 69.8 years). The mean bone mineral density of lumbar spine was -2.97 SD. Eleven patients had hypertension and 3 had diabetes mellitus. The treated levels included T10 (n = 2), T11 (n = 5), T12 (n = 9), L1 (n = 6), and L2 (n = 1). Significant defect of

the posterior vertebral wall and loss of vertebral height were found in 20 patients in KP group, and 11 in SSF + VP group. Twenty-nine of 54 patients had a history of minor trauma and mild back pain and returned to normal life after a short period of rest and symptomatic treatment. Progressive backache developed after a relatively asymptomatic period of time ranging from 2 to 9 months. The pain was relatively constant and became worse when changing position. Patients with neurological deficit were excluded. Radiographic examination showed progressive collapse of the vertebral fracture, intravertebral cleft, bone absorption, and sclerosis of the residual bone. Abnormal motion was shown on dynamic lateral x-ray films (Table 1).

In 1950s, the Steel classification was introduced to divide Kümmell's disease into 5 stages: Stage I, traumatic stage with no obvious abnormalities or only mild compressive vertebral fracture on x-ray films, and no physical dysfunction. Stage II, relatively asymptomatic stage with no loss of function. Stage III, subclinical period with varying degrees of symptoms, but no loss of basic function. Stage IV, recurrence with gradually worsening low back pain. Stage V, terminal stage with obviously kyphotic deformity, accompanied with cord compression. In 2004, the more practicable Li classification was adopted which consisted of three 3 (3): Stage I, body height loss < 20% with no adjacent degenerative disc disease, disc space narrowing, back pain, or symptoms. Signal changes were seen using vertebral magnetic resonance imaging (MRI). Stage II, body height loss > 20% with adjacent degenerative disc disease, dynamic mobile fracture, and back pain with or without radiculopathy. Stage III, serious loss of vertebral height, posterior cortex breakage with cord compression, and back pain with or without cord injury. The KP group consisted of 24 stage IV patients and 7 stage V patients, according to the Steel classification, or 24 stage II patients and 7 stage III patients, according to the Li classification. The SSF + VP group consisted of 18 stage IV patients and 5 stage V patients, according to the Steel classification, or 18 stage II patients and 5 stage III patients, according to the Li classification (Table 1).

#### **Preoperative Preparation**

A comprehensive assessment of the patients' general condition was performed. Standard anteroposterior and lateral radiographs, dynamic lateral x-ray films, computed tomography (CT) imaging (included sagittal and coronal reconstruction), and MRI were used to

Characteristic	KP group (n = 31)	SSF+VP group (n = 23) 3:20	
Gender (male: female)	6:25		
Mean age in years (range)	72.8 (61 - 83)	69.8 (64 - 76)	
Level of fracture (No. of patients)	T11 (6), T12 (15), L1 (8) , L2 (2)	T10 (2),T11 (5), T12 (9), L1 (6) , L2 (1)	
Stage (No. of patients)			
Steel classification	Stage IV (24) Stage V (7)	Stage IV (18) Stage V (5)	
Li classification	Stage II (24) Stage III (7)	Stage II (18) Stage III (5)	
Comorbidities (No. of patients)	·		
Hypertension	14	11	
Diabetes	6	3	

Table 1. Clinical characteristics of patients (n = 54).

evaluate the defects in the peripheral wall of the vertebra, especially the defect in the posterior wall, and to plan the surgical approach for needle insertion.

#### **Surgical Procedure**

Kyphoplasty was performed with the patient in a prone, lordotic position, with pillows under the upper chest and pelvis to facilitate the reduction of the fractured vertebral body. Using C-arm fluoroscopy visualization, bilateral transpedicular puncture was performed. After reaching the posterior margin of the vertebral body, bone needles were exchanged for a working cannula and a sample of residual bone was removed for histologic analysis. Bilateral balloon placement under the endplate was performed. Balloons were inflated gently with radio-opague media and deflated after elevating the superior endplate and achieving height restoration and kyphosis correction. The pre-formed cavity was filled with polymethylmethacrylate (PMMA) cement after the balloon was withdrawn; C-arm fluoroscopy was used to monitor cement distribution and avoid leakage.

For SSF + VP group, the patient was in same prone position, a posterior midline incision was adopted to expose one level above and one level below the affected vertebra, 4 pedicle screws were inserted and fixed with rods, after the achievement of a gentle reduction, bilateral transpedicular puncture, biopsy, and cement augmentation were performed for the fractured vertebra under fluoroscopy. Posterolateral fusion was used with allograft at the same time.

#### **Postoperative Treatment**

Patients were kept in the supine position for 2 hours. Vital signs, sensation, and motion in the lower extremities were monitored for 12 hours after surgery.

Antibiotics were given for one to 2 days. The patients began standing and walking one to 3 days after surgery depending on symptom improvement. Patients were discharged from the hospital 3 to 5 days after surgery with instructions including anti-osteoporosis treatment and use of a waist guard.

## **Assessment Indices**

Back pain was evaluated using a visual analogue scale (VAS: 0 = no pain at all, 10 = worst pain imaginable). Radiographs were taken to measure the anterior and posterior vertebral heights and local kyphotic angle (Cobb's method) of the fractured vertebral body before surgery, after surgery (one month after operation), and at the last follow-up. All radiographic measurements were performed in a double-blinded fashion by 2 physicians.

# **Statistical Analysis**

All data were expressed as mean  $\pm$  SD. Pre- and postoperative measurement data including VAS score, anterior and posterior heights of the fractured vertebral body, and local kyphotic angle were compared using a paired student's t-test. Pearson correlation coefficients were calculated to assess the relationship between the decreased values of pain scores (VAS) and improvement of anterior vertebral height and local kyphotic angle. P < 0.05 was considered to indicate statistical significant difference.

# RESULTS

# **Clinical Outcomes**

All 54 patients tolerated the operation well. For the KP group, the average operation time was 76 min-

utes (range, 60 – 95 minutes), and the average volume of cement injected was 4.7 mL (range, 3.5 - 6.5 mL). Blood loss during the operation was minimal. The average time of hospital stay was 4.3 days. Patients had follow-up from 8 to 36 months (mean: 19.8 months). The VAS pain score decreased significantly, from a preoperative value of  $7.8 \pm 0.9$  to a postoperative value of  $3.3 \pm 1.0$  (P < 0.001). The score decreased further to 2.9 ± 0.9 at final follow-up. This was not significantly different from the postoperative value (P = 0.115). The mean preoperative anterior vertebral body height was 14.8  $\pm$  2.4 mm and increased to 19.3  $\pm$  2.1 mm (P < 0.001) after surgery. The mean preoperative local kyphotic angle was 22.7  $\pm$  6.9° and improved to 14.5  $\pm$  5.3° (P < 0.001) after surgery. During the operation, there were no serious toxic reactions to PMMA (circulatory collapse, shock, or cardiac arrest, events which would stop the procedure). Four intradiscal, 3 paravertebral, and 4 intracanal cement leakages were identified without neurological deficits. After surgery, all patients had significant relief of back pain, were able to walk, and could take care of themselves. There was no significant loss in the height or the kyphotic angle of the treated vertebra on final follow-up (Table 2). The improvement of VAS score had no significant correlation with the

improvement of vertebral height (r = 0.163, P = 0.372) or local kyphotic angle (r = -0.288, P = 0.110) (Table 3).

For the SSF + VP group, the average operation time was 128 minutes (range: 95 - 165 minutes), and the average volume of cement injected was 4.3 mL (range: 3.3 – 6.5 mL). Blood loss during the operation was 245 mL. The average time of hospital stay was 7.2 days. Patients had follow-up from 12 to 42 months (mean: 21.6 months). The VAS pain score decreased significantly, from a preoperative value of  $7.2 \pm 1.6$  to a postoperative value of  $4.7 \pm 1.3$  (P < 0.05). The score decreased further to  $3.5 \pm 1.2$  at final follow-up. This was not significantly different from the postoperative value (P = 0.146). The mean preoperative anterior vertebral body height was  $13.6 \pm 2.5$  mm and after surgery was  $17.3 \pm 2.7 \text{ mm}$  (P < 0.05). The mean preoperative local kyphotic angle was 24.7 ± 9.2° and after surgery was  $15.5 \pm 6.2^{\circ}$  (P < 0.001). A small amount of cement leakage was observed in 4 patients, and one intracanal leakage accepted prophylactic decompression, no neurological deterioration was found postoperatively. There was no significant loss in the height or the kyphotic angle of the treated vertebra on final follow-up (Table 4). One patient underwent hardware removal 4 months after surgery because of loosening of the distal

Table 2. Comparison of VAS score, vertebral height, and kyphotic angle (n = 31).

	VAS score	Anterior vertebral height (mm)	Posterior vertebral height (mm)	Kyphotic angle(°)
Preoperative	$7.8 \pm 0.9$	$14.8 \pm 2.4$	$21.8 \pm 2.1$	$22.7\pm6.9$
Postoperative	$3.3 \pm 1.0^{*}$	19.3 ± 2.1*	$22.2 \pm 1.8$	14.5 ± 5.3*
Final follow-up	2.9 ± 0.9*	17.9 ± 2.2*	21.9 ± 1.7	15.5 ± 5.2*

\*Significant difference at P < 0.05 compared with before surgery

Table 3. Correlation coefficient (r) between the decreased values of VAS and improvement of the anterior vertebral height and local kyphotic angle (n=32).

	Post-operation+		Final follow-up+		Final follow-up◊	
	r	Р	r	Р	r	Р
ΔAVH	0.163	0.372	-0.026	0.889	-0.290	0.108
ΔLKA	-0.288	0.110	0.154	0.399	-0.059	0.748

• Compared with pre-operation

Ocompared with post-operation

Table 4. Comparison of VAS score, vertebral height, and kyphotic angle (n = 23).

	VAS score	Anterior vertebral height (mm)	Posterior vertebral height (mm)	Kyphotic angle(°)
Preoperative	$7.2 \pm 1.6$	13.6 ± 2.5	21.8 ± 2.5	24.7 ± 9.2
Postoperative	4.7 ± 1.3*	$17.3 \pm 2.7^{\star}$	$22.4 \pm 1.8$	15.5 ± 6.2*
Final follow-up	3.5 ± 1.2*	17.7 ± 2.3*	22.1 ± 1.9	15.8 ± 5.6*

\*Significant difference at P < 0.05 compared with before surgery

pedicle screws. The improvement of VAS score had no significant correlation with the improvement of vertebral height (r = 0.184, P = 0.391) or local kyphotic angle (r = -0.273, P = 0.145. (Table 5).

### **Illustrative Case**

A 76-year-old woman experienced a minor fall at home, which led to her back pain. X-ray films showed mild compression of the T12 vertebra. MRI indicated low signal intensity using T1W1 SE sequence, and high signal intensity using T2WI. STIR sequence demonstrated high signal, consistent with edema due to the fracture at T12 (Fig. 1). The symptoms were relieved after a week of bed rest, and she returned to normal life activities. However, 4 months after the initial injury, vertebral pain recurred, and gradually led to difficulty in getting up and walking. X-ray films 6 months later showed bone absorption, collapse, and dynamic mobile fracture of the T12 vertebra. CT scan showed an intravertebral vacuum cleft, osteosclerosis, and a defect in the posterior cortex (Fig. 2). She was treated with balloon kyphoplasty (Fig. 3). Intraoperative biopsy showed bone necrosis. The patient had significant pain relief and returned to normal life activities after surgery. At the time of final follow-up (16 months after surgery), she reported mild back pain with no significant loss of corrected vertebral height and kyphosis (Fig. 4).

#### Discussion

In our study, both kyphoplasty and short segmental fixation combined with vertebroplasty achieved satisfactory outcome for Kümmell's disease with regard to backache relief, kyphosis correction, and vertebral height restoration. There was no statistical difference between the 2 groups with regard to pain reduction and radiographic outcome. Although both group had asymptomatic minor cement leakage, all the patients tolerated the operation well, suggesting both procedures were safe and effective. These results were comparable with previous studies (10-13). Comparatively, the SSF + VP group required a significantly longer operation time and hospital stay at greater costs.

The pathogenesis of intravertebral cleft or vacuum phenomenon remains controversial and it has been mainly theorized to involve avascular necrosis, fracture nonunion or pseudarthrosis, or intradiscal gas leakage into the vertebral body. Each of these theories can explain the cause of Kümmell's disease to a certain extent (14-16). The causes of pain in Kümmell's disease are also multifactorial, due mainly to micro-movement of the

Table 5. Correlation coefficient (r) between the decreased values of VAS and improvement of the anterior vertebral height and local kyphotic angle (n = 23).

	Post-operation+		Final follow-up+		Final follow-up◊	
	r	Р	r	Р	r	Р
ΔAVH	0.184	0.391	-0.029	0.892	-0.295	0.118
ΔLKA	-0.273	0.145	0.164	0.402	-0.063	0.756

Compared with pre-operation

 $\Diamond$  Compared with post-operation

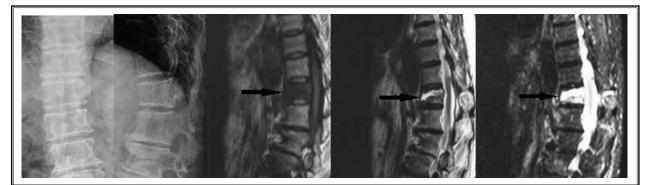


Fig. 1. After the initial injury, x-ray films showed mild T12 vertebral compression. The MRI indicated edematous signal changes and a fluid filled cleft of the fractured vertebra (low-signal-intensity on T1-weighted image, high-signal-intensity on T2-weighted image, and much higher signal intensity using an inversion recovery sequence).

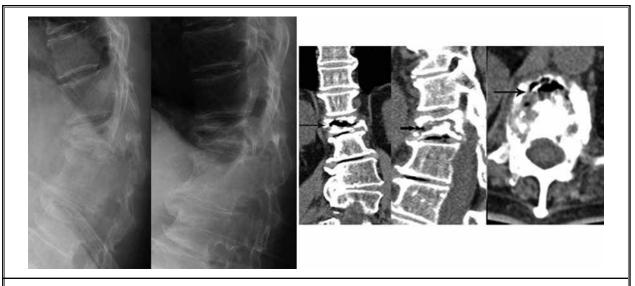


Fig. 2. Six months after the initial injury, severe vertebral collapse and dynamic mobile fracture of the T12 vertebra were identified. CT scans showed an intravertebral vacuum cleft, sclerosis, and defect of the peripheral cortex, including the posterior cortex of the affected vertebral body.



Fig. 3. During the kyphoplasty, the balloon was placed in the cleft of the vertebra to restore the vertebral height and to correct the kyphosis. After the balloon was withdrawn, bone cement was injected to fill the gap and stabilize the fracture.

vertebral fracture. Effective pain reduction and satisfactory clinical outcomes can be obtained after elimination of the microfractures and vertebral stabilization (17-19).The treatment strategies for Kümmell's disease differ between patients with neurological symptoms and those without neurological symptoms. For neurological impaired patients, the aim of surgery is to decompress the spinal canal, restore the spinal curvature and main-

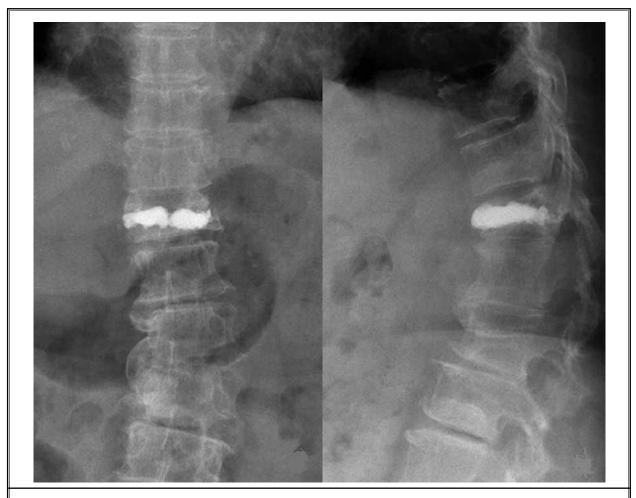


Fig. 4. X-ray films showed no significant loss of correction of vertebral height or kyphosis after 16 months of follow-up.

tain spinal stability. The surgical modes include anterior, posterior, or combined anterior and posterior approaches. For patients without neurological symptoms, the objective is to eliminate motion at the fracture site and restore the spinal curvature. Certain authors have reported that VP or KP achieved good clinical results for Kümmell's disease without neurological symptoms. These minimally invasive procedures were thought to be optimal for older patients with comorbidities, and postoperative rehabilitation was easy to carry out early (20,21). Consistent with previous studies, we also found significant pain reduction and good mid-term outcome following kyphoplasty. Pain relief after kyphoplasty is generally believed to result from the stabilization of the fractured vertebrae and elimination of microscopic and/or macroscopic motion at the fracture site. Other postulated mechanisms of pain relief include a chemical

or thermal neurolytic effect of PMMA (22-25).

However, despite the enthusiasm for kyphoplasty or vertebroplasty, Kümmell's disease is different from common osteoporotic vertebral compression fractures and characterized by bone absorption and sclerosis. The majority of Kümmell's disease patients were diagnosed in the late-stage, with severe backache and kyphosis. The pattern of cement filling is quite unique. For most patients, cement augmentation acts as a supporting block, because of the lack of cement diffusion into trabecular bone, the locking effect between bone and cement is insufficient. Two case reports have focused on delayed cement displacement following PVP or PKP alone for Kümmell's disease without neurological deficits (26,27). In 2011, Lee et al (9) reported satisfactory results for 10 patients with Kümmell's disease treated by vertebroplasty combined with short segmental fixation. Our retrospective study found that although the short segmental fixation combined with vertebroplasty also achieved good clinical outcome, kyphoplasty alone can obtain comparable satisfactory results for Kümmell's disease with less complications.

The relationship between the severity of back pain and hyperkyphosis in osteoporotic vertebral compression fracture was another controversial issue. Ettinger et al (28) measured 2,992 white women aged 65 – 70 years and found that vertebral deformities cause substantial pain, disability, or loss of height if vertebral height ratios fall 4 SD the normal mean. Ryan et al (29) investigated the pain and disability experienced by postmenopausal women, and reported that symptoms were related to the number of vertebral deformities, and degree of kyphosis. On the contrary, another previous study found that the improvement of VAS score had no correlation with the improvement of vertebral height or local kyphotic angle (25).

Our study did not find an association between backache relief and kyphosis correction. The VAS score decreased significantly, and the anterior vertebral height and local kyphotic angle also improved significantly after kyphoplasty. However, the improvement of the VAS score had no significant correlation with the improvement of anterior vertebral height or local kyphotic angle. This suggests that the severity of back pain might be unrelated to the severity of the kyphosis or the vertebral height loss. Moreover, previous studies reported that although kyphoplasty had a better effect on reduction of vertebral compression fractures than vertebroplasty did, it was not superior to vertebroplasty in pain relief (30,31). This suggests that correction of vertebral height and local kyphosis might not be the main factor in pain reduction.

Limitations of this study included that it was a retrospective analysis, no method was adopted to ensure unbiased randomization of the 2 groups. Second, both groups included older patients with comorbidities, the influence of which was not analyzed. Third, the followup period differed significantly from 8 months to 42 months. Despite the above-mentioned limitations, this study assessed and compared the clinical outcome of 2 commonly used procedures for a relatively difficult disease, and provided important information.

# CONCLUSION

This study showed that both balloon kyphoplasty alone and vertebroplasty combined with short segmental fixation for Kümmell's disease are safe and effective. Comparatively, balloon kyphoplasty resulted in the same clinical outcomes with fewer complications.

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